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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193
24239	7590	09/15/2006	EXAMINER	
MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			BOESEN, AGNIESZKA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/684,026	<b>Applicant(s)</b> DEVICO ET AL.	
	<b>Examiner</b> Agnieszka Boesen	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6-9, 11, 13-16, 24, 34, 35, 37, 38, 40-46, 49-57, 60-63, 65 and 73-85 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 37, 38, 40-46, 49-57, 60-63 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3, 6-9, 11, 13-16, 24, and 73-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. .  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In the telephone interview between Applicant's representative Marianne Fuierer and Examiner Agnieszka Boesen on August 31, 2006, allowable subject matter was discussed as well as possible Examiners amendment. However no agreement was reached. It is acknowledged that Terminal Disclaimer has been filed on August 31, 2006 over claims of US Patent 6,908,612 B2.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

The Amendment filed June 6, 2006 is acknowledged and has been entered. Claims 1-3, 6-9, 11, 13-16, 24, 73-79 and new claims 80-85 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

***Claim Rejections - 35 USC § 112***

The rejection of claims 1-3, 6-11, 13-16, 24 and 73-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicant's arguments and amendments to the claims.

New rejections

***Claim Rejections - 35 USC § 112***

**Claims 1 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The term "about 95%" is vague and indefinite. It is not clear what are the metes and bounds of term "about 95%."

**Claims 1-3, 6-9, 11, 13-16, 24, and 73-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-3, 6-9, 11, 13-16, 24, and 73-85 are drawn to a chimeric polypeptide comprising a virus coat polypeptide, a viral cell surface receptor polypeptide, an amino acid sequence spacer, wherein the amino acid sequence of the chimeric polypeptide is a full length reference sequence, a truncated sequence or a modified sequence, wherein the modified sequence

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has about 95% identity to the full length reference sequence, wherein the chimeric polypeptide has functionality of forming an intramolecular complex and interacting with or blocking a cellular co-receptor that is utilized by a virus for infection.

While the specification provides the evidence that gp120-CD4 chimeric molecules, containing a CCR5-specific HIV envelope bind to and block CCR5 cellular receptor, the specification provides no exemplification of a chimeric polypeptide, which amino acid sequence is a truncated or modified, forming an intramolecular complex and interacting with or blocking a cellular co-receptor that is utilized by a virus for infection.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

It is largely unpredictable how the truncations and modification of the chimeric polypeptide will affect the functionality of the chimera to form an intramolecular complex and to interact with or block a cellular co-receptor, which virus utilizes for infection. See the following publications that support this unpredictability (Baker et al., Protein structure prediction and structural genomics. Science (2001) Vol. 294, No. 5540, pages 93- 96; Attwood, T. The babel of bioinformatics. Science (2000) Vol. 290, no. 5491, pages 471-473). The scope of the invention is very broad, encompassing a large number of polypeptide sequences that may or may not preserve the claimed functionality of the chimeric polypeptide. As stated above, the teaching

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in the as-filed specification is not commensurate in scope with the claims because the breadth of the claims embraces a large number of possible polypeptide sequences comprising the chimera.

In conclusion, the as-filed specification and the claims coupled with the art of record at the time the invention was made do not provide sufficient guidance and/or evidence to reasonably enable making and using a chimeric polypeptide comprising a virus coat polypeptide, wherein the amino acid sequence of the chimeric polypeptide is truncated or modified.

One would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the In Re Wands Factors including the lack of guidance in the application's disclosure and the unpredictability of producing a chimeric polypeptide wherein the amino acid sequence is truncated or modified. Thus, the lack of working examples, lack of guidance in the specification and the prior art, the unpredictability of the art of protein engineering and the great breadth of the claims greatly reduces the probability that one of skill in the art would successfully obtain the claimed invention without undue experimentation.

Response to Applicants remarks regarding Rejoinder of Method Claims

Applicant requested rejoinder of process claims in case the product claims are found allowable. Applicant argues that the currently pending method claims include all the limitations of the product claims and meet the standard of enablement, written description and definiteness.

Applicant is advised that in case the product claims are found allowable method claims 34, 35, 37, 38, 40, and 41-45 are eligible for rejoinder.

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Claims 46, 49-57, 60-63, and 65 are not eligible for rejoinder because the currently withdrawn process claims 46, 49-57, 60-63, and 65 are not commensurate in scope with the product claims 1-3, 6-9, 11, 13-16, 24, and 73-85.

[MPEP § 821.04(b)] Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Claims 46, 49-57, 60-63, and 65 are drawn to a method for identifying an agent that inhibits an interaction between virus and virus co-receptor comprising steps of contacting the chimeric polypeptide with a virus co-receptor and detecting binding. The product claims 1-3, 6-9, 11, 13-16, 24, and 73-85 do not encompass various types of agents that are used in the process claims 46, 49-57, 60-63, and 65. Therefore the process claims are not commensurate in scope with the product claims and thus process claims 46, 49-57, 60-63, and 65 are not eligible for rejoinder

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.  
Examiner

9/14/06

*Stacy B. Chen* 9/14/06  
STACY B. CHEN  
PRIMARY EXAMINER